

Application No. 10/828,508

Docket No.: 101896-232

**REMARKS****Status of the Claims**

Following entry of this amendment, claims 22-92, including five independent claims (22, 37, 56, 67, and 80) are pending in this application. The Examiner has rejected all claims. Claims 77, 78 and 91 are canceled by this Amendment. Upon entry of this amendment, claims 22-76, 79-90, and 92 will be pending in this application. Claim amendments made herein only conform language in dependent claims to correct antecedent bases, or to move elements between claims -- no new matter is added.

Applicants thank Examiner Araj and Primary Examiner Robert for the courtesy they extended during a telephonic interview on February 15, 2006, and certain amendments made herein are reflective of the issues discussed during that interview.

Of the five pending independent claims, three are amended herein. Claims 22 and 37 are not amended, and Applicants rely on the comments made below. Claims 67 and 80 have been amended to reflect that a plurality of flanges having inferior contact surfaces are provided on each sidewall of the head. These amendments are supported in the application at least at page 5, line 26 to page 6, line 3 (describing Figure 2A) and page 10, lines 13 to 23 (describing Figure 7B). Regarding claim 56, the claim has been amended to recite that the locking element comprises a protrusion and groove that engage when the cap is rotated to a closed position with respect to the anchoring element. This amendment is described in the application at least at page 10, lines 24 to 28.

**Double Patenting**

The Examiner has rejected all claims 22-92 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,755,829 (Bono et al.). In particular, the Examiner asserts:

Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the application claims and the patent claims lies in the fact that the patent claims include more elements and are thus much

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specific. Thus the invention of the patent claims are in effect a "species" of the "generic" invention of the application claims. It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since the application claims are anticipated by the patent claims, they are not patentably distinct from the patent claims.

While the Applicants disagree with the bases for the Examiner's conclusion of obviousness-type double patenting, Applicants provide herewith a Terminal Disclaimer for the purpose of obviating the obviousness-type double patenting rejection. This Terminal Disclaimer should not be taken as any kind of admission, and is provided solely for the purpose of expediting prosecution of the present application.

#### **Claim Rejections Over Prior Art**

The Examiner has rejected all of the claims of the pending application over a single prior art reference: US 5,257,993 to Asher et al. (referred to herein as "Asher"). Applicants note that all of the claims in the parent to the pending application were allowed over Asher (see, in particular, the Office Action mailed on March 20, 2003 (Paper No. 9) in parent application no. 09/667,937 (now US 6,755,829) in which all prior art based rejections were made over Asher), despite the fact that many of the pending claims are in some ways more specific and narrowly tailored than the claims in the parent that were allowed over Asher (for example, claim 1 of US 6,755,829 does not require the radial slant of pending claim 22). Applicants submit, as explained in detail below, that the present claims are patentable over Asher for all of the reasons that the claims in the parent were patentable over Asher, as well as for a number of further reasons additionally recounted below.

#### **Claim Rejections Under 35 U.S.C. §102**

The Examiner has rejected claims 22-26, 29-42, 45-64, 67-77 and 80-90 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,257,993 (Asher et al.). In particular, the Examiner asserts:

Asher et al. disclose an anchor assembly comprising an anchor assembly (22) having an anchor element (28) with an axis, and a head member (26) with

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an open slot (32). The anchor element can be a hook or screw or post (see Figure 1 and col. 11, lines 65-68). The assembly further comprises a cap (24). The head member has two side walls having at least a flange portion (68 and 70) extending generally transverse to the central axis. The cap includes a cover having a plurality of spaced apart radially extending flanges or rim portions (74,76). The cap also includes a clamping member (60), i.e. a screw or bolt, which can be separately tightened with respect to the closure element to which it is rotably connected. The head member and cap twist-lock together by engagement of respective flange segments. The flange segments have inferior contact surfaces that are sloped to provide a radial slant and that engage with superior contact surfaces of the cap that also have a radial slant (see Figure 22). The assembly also has a stop (114).

Claim Rejections Under 35 U.S.C. §103

The Examiner has rejected claims 27, 28, 43, 44, 65, 66, 78, 79, 91 and 92 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,257,993 (Asher et al.). In particular, the Examiner asserts:

Asher et al. disclose everything except a plurality of flange segments on each side wall that are configured so that the closure element can be moved from the open to the closed position by twisting the closure element by less than or equal to about twenty degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the assembly of Asher et al. having a plurality of flanges, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8. With regard to claims 28, 44, 66, 79 and 92, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the assembly of Asher et al. with the configuration allowing an open to closed position formation by twisting the closure element by less than or equal to about twenty degrees, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

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The Asher Reference

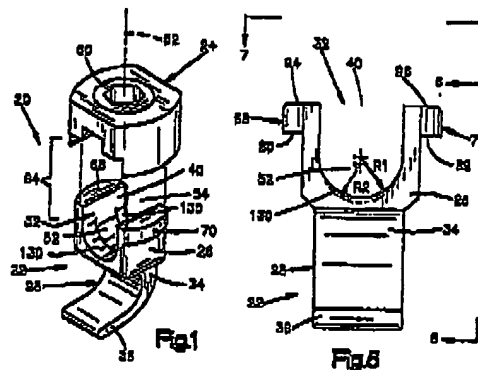
The Asher reference, assigned on its face to a predecessor corporation to the assignee of the present application, discloses "a top-entry hook assembly having a hook portion which is engageable with a spinal column" that includes a body and an end cap. [Abstract.] "The end cap and body are inter-connectable by different types of connectors including a bayonet connector, a linear cam connector, or a threaded connector." [Id.]

Asher identifies six distinct embodiments in his disclosure. Asher's first embodiment, illustrated in Figures 1 through 10, is entitled "Hook Assembly - Bayonet Connector." This embodiment, illustrated in Figures 1 and 5 provided below. As can be seen in the Figures,

The top-entry hook assembly 20 includes a one-piece, metal, hook portion 22 and a metal end cap 24. The hook portion 22 includes a generally rectangular body 26 and a downwardly extending hook. [Column 3, lines 61 to 64.]

Importantly, the body and the end cap are provided with two flanges each (68, 70 and 74, 76, respectively) - one on each sidewall, so that,

When the end cap 24 is connected to the hook portion 22, flat bottom surfaces 80 and 82 on the hook portion flanges 68 and 70 engage flat inwardly facing surfaces on the flanges 74 and 76 on the end cap 24. [Column 5, lines 27 to 31.]



As is clear from the text and from the Figures - the engaging surfaces on the flanges are flat - perfectly horizontal, there is no radial slant.

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The Asher device of this embodiment further operates as follows:

The end cap 24 is then **rotated through 90°** relative to the hook portion 22. After the end cap has been **rotated through 90°**, a stop surface 114 (FIG. 9) formed in the end cap 24 abuttingly engages one of the flanges 68 and 70 on the hook portion 22. The **stop surface 114 blocks further rotation** of the end cap 24 relative to the hook portion 22. [Column 5, line 66 to column 6, line 4.]

That is, the cap is rotated 90 degrees (no less) and then engages a stop surface that prevents further rotation (but does not lock – it does not prevent backing out of the cap).

The second embodiment of Asher, the “Hook Assembly – Linear Cam Connector,” is disclosed in Figures 11 to 14 of Asher. This embodiment is said to be similar to the first embodiment, except that “the end cap and hook portions are interconnected by linear flange surfaces.” [Column 6, line 67 to column 7, line 1.] This end cap is engaged to the hook portion by a linear engagement – it is not rotated at all. Here the flanges are linear, but they are cammed so that the end cap is drawn down as it is moved linearly into engagement with the hook portion.

The third embodiment of Asher relates to a “Hook Assembly – Threaded Connector.” This embodiment, illustrated in Figures 15 to 17, has no flanges but instead has an end cap that engages the body through a threaded connection.

The fourth embodiment of Asher is, according to the “Brief Description of the Drawings,” depicted in Figures 18 and 19 – however, the only description of these Figures can be found in the description of the First Embodiment, where Asher provides:

If the rod 48 has a relatively small cross section the recess 32 (FIGS. 18 and 19) of the hook portion 22 includes vertical slots 140 in the sides of the upper side opening 40. The set screw 60 extends into the vertical slots 140 when the end cap 24 is connected with the hook portion 22. [Column 6, lines 56 to 61.]

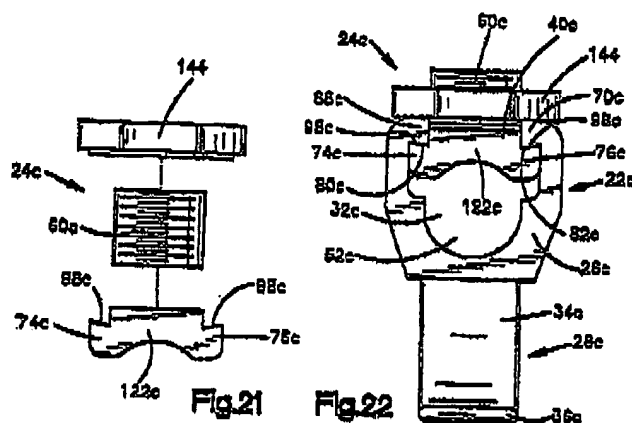
The fifth embodiment of the Asher disclosure, entitled “Hook Assembly – Internal Cap Connector,” is another side entry or linear entry end cap embodiment:

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The end cap 24c (FIG. 21) has a pair of linear flanges 74c and 76c which extend outwardly from a base portion 122c of the end cap. When the end cap 24c is moved along a linear path onto the hook portion 22c, upper side surface 98c of flanges 74c and 76c engage lower side surfaces 80c and 82c of flanges 68c and 70c (FIG. 22). [Column 8, lines 56 to 61.]

As can be seen in Figures 21 and 22 below, these flanges are provided with a slant – but the end cap does not rotate into place and the slant is not a *radial* slant as the flanges are linear. In addition this embodiment provides a locking nut 144 which is said to threadably engage “the set screw 60c to clamp the flanges 68c and 70c of the body portion 26c between the lock nut and the flanges 74c and 76c of the end cap 24c to further hold the end cap against movement relative to the hook portion 22c.” This “lock nut” is not integral with the cap but is a separate element that is threaded onto the set screw which is in turn threaded into the cap.



Figures 23 to 26 illustrate the sixth and final embodiment of the Asher reference. In this embodiment, which is similar to the first embodiment, but does not include the retainer walls 102, 104, 106 and 108 of that embodiment.

In a conclusion section, the Asher reference provides that “the connector designs described above could be used on a screw or post to attach a rod to the screw or post.” The disclosure of Asher provides no further details, in particular, it never discloses a pedicle screw or a polyaxial pedicle screw.

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*Response to Rejections Regarding Claims 22 to 55*

This group of claims includes two independent claims (22 and 37) that recite an anchor element and cap assembly where the cap is *rotated* into engagement with a head of the anchor element and flanges are provided on the head and cap for engagement – the flanges having engaging surfaces that are *angled along a radial direction or that have a radial slant*. Asher does not anticipate these claims.

In order to anticipate a claim, “each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Still further, in the reference “*the elements must be arranged as required by the claim.*” MPEP § 2131, citing *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

Asher does not disclose a rotating cap with flange engagement surfaces having a radial slant. Asher does disclose rotating caps with flat engagement surfaces on its flanges. Asher also discloses a linear cap with slanted flange surfaces (though not radial because the cap is linear). There is no disclosure in Asher that shows the claimed elements arranged in the manner recited in the claims. Accordingly independent claims 22 and 37, as well as the claims that depend from claims 22 and 37, cannot be anticipated by Asher.

Claims 24 and 53 depend from independent claims 22 and 37, respectively. Each of these claims recites that the anchor element is a polyaxial screw. These claims stand rejected as anticipated. Asher does not disclose, teach or suggest polyaxial pedicle screws. Asher does disclose that the described closure mechanism can be used with screws or posts – but never mentions polyaxial pedicle screws. As there is no disclosure in Asher of this recited claim element, there can be no anticipation of either claim 24 or claim 53.

Claims 27 and 28, as well as claims 43 and 44, recite *a plurality of flange segments* (or radially protruding elements) *on each sidewall* of the anchor that forms the open slot in which the rod received into the anchor element and further that the plurality of flange segments are arranged to *allow the closure element (or cap) to be closed by twisting the closure element by less than or equal to about 20 degrees* as follows:

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Claim Number	Depends From	Recitation	Claim Number	Depends From	Recitation
27	22	a plurality of anchor flange segments are provided on each side wall [of the head]	43	38	a plurality of radially-protruding elements are provided on each side wall [of the head]
28	27	the plurality of anchor flange segments provided on each side wall are configured so that the closure element can be moved from the open to the closed position by twisting the closure element by less than or equal to about twenty degrees	44	43	the plurality of radially-protruding elements provided on each side wall are configured so that the cap can be moved from the open to the closed position by twisting the closure element by less than or equal to about twenty degrees

Each of these four claims stands rejected as obvious over Asher. Regarding the use of multiple flange segments, the Examiner states that

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the assembly of Asher et al. having a plurality of flanges, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

The provision of multiple flanges on each sidewall is not a "mere duplication of the essential working parts" and the citation to *St. Regis Paper* is inapt. In fact, resort to the actual text of *St. Regis Paper* shows that these claims are not obvious:

Moreover, the Supreme Court has recently indicated that section 103 cannot easily be satisfied by inventions that rearrange old elements in new combinations with each element performing the same function it performed in the prior art, even though the new combination produces a more striking result than the old ones. Unless the combination is "synergistic, that is, 'result[ing] in an effect greater than the sum of the several effects taken separately,'" it cannot be patented. [Citations omitted.]

Turning then to the facts of that case (a bag with multiple plies), the *St. Regis Paper* court found:

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The [claimed] bag consists of four elements: (1) it has gussets; (2) it uses a pinch bottom; (3) it has the three-step feature at the top and bottom; and (4) it has multiple layers. [Defendant] argues that [the prior art] incorporates a bag with the first three elements of the [claimed] bag. An examination of the [prior art] shows that this claim is correct.

[Defendant] has further demonstrated that the fourth element of the [claimed] bag, its use of multiple layers to achieve the effect of many bags within one, has been known in the bag industry for many years. In fact, St. Regis admitted during the course of litigation that it has sold gusseted multiwall bags in the United States since the early 1930's.

Therefore, the [claimed] bag is only entitled to a patent if the fusion of the old elements that comprised the [prior art bag] and the old element of multiple layering created a synergistic combination. We hold that it did not do so. . . .

The presently claimed invention is not such a "mere duplication." Rather, as *St. Regis Paper* notes, these claims should be patented because the recited elements are combined to a synergistic end. In particular, the provision of multiple flanges on each end wall makes it possible to design a closure system that can be sealed with a short twist, allowing a surgeon to close it with a simple one-handed motion. This synergistic advantage flowing from providing a plurality of flanges on each end wall is described in the application at least at page 6, lines 5 to 29. Far from being the "mere duplication" of features provided for an art recognized reason, these claims recite a novel configuration that provides previously unknown advantages.

Still further, unlike *St. Regis Paper*, the Examiner refers to no teaching or suggestion, from Asher or from the prior art as a whole, as to the effects of the so-called "duplication." In *St. Regis Paper*, prior art was cited for the proposition that multiple plies (the duplication) resulted in stronger bags. The patentee in that case had applied multiple plies for their art recognized reason. Here, there is no teaching or suggestion of providing multiple flanges, or of the advantage that is achieved by this configuration.

In fact, the person of ordinary skill in the art would be motivated *not* to invent the Applicants' configuration. Asher teaches flanges that extend along the entirety of the side walls of the head – no doubt in order to maximize the strength of the engagement between the flanges.

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Applicants' configuration – breaking up the flanges along the side walls into multiple flanges, would be seen as weakening the engagement but for the further engineering advances made by the Applicants that are disclosed in the present application and claimed in related applications.

Claims 27 and 43 are separately patentable over Asher above and beyond the independent claims from which they depend for these further reasons.

Referring now to claims 28 and 44 – these claims expressly recite the synergistic result of the multiple flange configuration. Namely, that the caps can be closed by a rotation of less than or equal to about 20 degrees. The Examiner says of this advance:

With regard to claims 28, 44, 66, 79 and 92, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the assembly of Asher et al. with the configuration allowing an open to closed position formation by twisting the closure element by less than or equal to about twenty degrees, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

This argument fails for two reasons. First, the configuration of Asher does not allow for a short twist closure, and indeed, every embodiment of Asher that includes a rotating cap involves a rotation of precisely 90 degrees. There is no teaching in the prior art of how to make a rotating closure in any other way.

Second, the reference to *In re Aller* is inapt. As the MPEP (*see* MPEP § 2144.05 II. B. "Only Result-Effective Variables Can Be Optimized") notes:

A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977)

There is no recognition in the art that the amount of twist required to close the cap is a result-effective parameter. Quite to the contrary, Asher only discloses, teaches and suggests exactly 90 degrees of rotation to close its cap. Before the engineering advances made by Applicants as

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disclosed in the pending application, closure by rotation of significantly less than 90 degrees (and the advantages that go therewith) were simply not known in the art. Rather than being art recognized as a result effect parameter – there was no suggestion in the art that these claim recitations were possible. Accordingly, claims 28 and 44 are separately patentable over Asher on this basis as well.

Claims 34, 35 and 36 and 50, 51 and 52 are also separately patentable over Asher. These claims recite features of a locking element as follows:

Claim Number	Depends From	Recitation	Claim Number	Depends From	Recitation
34	22	a locking element is provided on the closure element	50	37	a locking element is provided on the cap
35	34	wherein the locking element is configured to lock upon rotation of the closure element from the open position to the closed position	51	50	wherein the locking element is configured to lock upon rotation of the cap from the open position to the closed position
36	35	wherein, upon locking, the locking element deters the closure element from rotating back to the open position	52	51	wherein, upon locking, the locking element deters the cap from rotating back to the open position

These claims stand rejected as anticipated by Asher, however, Asher does not provide a locking element, much less one that is configured to lock upon rotation to the closed position or that deters the closure element from rotating back to the open position. The Examiner never identifies the element in Asher that is asserted to correspond to a locking element – the Examiner does say that the “head member and cap twist-lock together by engagement of respective flange segments” – but that position is unsupported and does not point to a locking element. The Examiner also identifies a “stop (114),” but, as noted above, the stop only prevents over-rotation – it does not lock and, in particular, it does not prevent the cap from rotating back to the open position.

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Response to Rejections Regarding Claims 56 to 66

This group of claims includes one independent claim, claim 56, that recites, *inter alia*,

a locking element comprising a protrusion and groove provided on the cap and anchor element and configured so that when the closure element is placed into the opening in the anchor element in an open position and is twisted into a closed position in which the closure element flange segments engage the and anchor element inferior surfaces to hold the closure in the opening, the protrusion and groove engage so that the locking element deters the closure element from twisting back to the open position.

This recitation of a locking element is substantially similar to that of claims 36 and 52 and is not anticipated by Asher for at least all of the same reasons that those claims are not – including 1) Asher does not disclose a locking element; 2) Asher does not disclose a locking element that locks upon twisting; and 3) Asher does not disclose a locking element that deters the closure element from twisting back to the open position.

Claims 62 and 63 recite a radial slant similar to that of claim 22, and is accordingly separately patentable over Asher as Asher does not disclose a twist cap having flanges with a radial slant.

Claims 65 and 66 recite a plurality of inferior surfaces provided on each side wall, and the plurality of inferior surfaces configured so that the closure element is closed by twisting the closure element by less than or equal to about twenty degrees. These recitations are similar to those of claims 27 and 28, as well as 43 and 44, and are patentable over Asher for at least all of the same reasons as those claims. Namely, the provision of multiple inferior surfaces on each side wall is not a mere duplication but a new configuration that provides a surprising new result; and the ability to close the closure element by twisting about 20 degrees or less is a new advantage that is not recognized by the art.

Response to Rejections Regarding Claims 67 to 92

This group of claims includes two independent claims (67 and 80), each of which recites a plurality of inferior surfaces provided on each side wall of the head of the implant. This feature is further refined by claims 79 and 92, each of which recites that the closure element can

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be closed by a rotation of less than or equal to about 20 degrees. These recitations are similar to those of claims 27 and 28, as well as 43 and 44, and are patentable over Asher for at least all of the same reasons as those claims as discussed extensively above. Namely, the provision of multiple inferior surfaces on each side wall is not a mere duplication but a new configuration that provides a surprising new result; and the ability to close the closure element by twisting about 20 degrees or less is a new advantage that is not recognized by the art.

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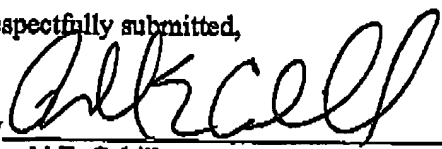
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**REQUEST FOR TELEPHONIC INTERVIEW**

Applicants believe that further prosecution of the pending application will best be served by a telephonic interview between the Examiner and Applicants' representative. Undersigned counsel for the Applicants will telephone the Examiner to arrange an appropriate time for the interview.

Dated: February 16, 2006

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